



HOPA News

Institute for Safe Medication Practices (ISMP) Reports: Medication Safety Concerns with Drugs Used in Oncology Patients

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ISM Reports is a new column that will appear regularly in *HOPA News* and will highlight actual incidents that have been reported to the ISMP and/or the FDA. It is written by Ray Muller, Associate Director, Division of Pharmacy Services at Memorial Sloan-Kettering Cancer Center. Ray is a nationally recognized medication safety expert and a member of ISMP's clinical practitioner advisory board.

Fatal Vindesine Event

A 25-year-old woman receiving treatment for non-Hodgkin's lymphoma died after receiving vindesine intrathecally (Death due to intrathecal vindesine. *Prescribe International*. 2008;17:153). Her physician confused a syringe of IV vindesine with a syringe of methylprednisolone meant for intrathecal injection. Intrathecal injections of all vinca alkaloids (vincristine, vinblastine, and vinorelbine) are almost universally fatal (see Muller RJ, Kloth DD, Friese C. Designing strategies to prevent cancer chemotherapy errors - Part 1. *Clinical Oncology News*. 2006;Nov/Dec:51-56.)

To prevent this type of error, vinca alkaloids should never be in the same treatment room as intrathecal medications. From an order entry standpoint, this error could be prevented if the pharmacy system had an automatic dead stop whenever a pharmacist tries to enter a vinca alkaloid, doxorubicin, or daunorubicin by the

intrathecal route. All manufacturers of vinca alkaloids are required to include auxiliary warning labels that state "FATAL if given intrathecally. FOR IV USE ONLY." Tragic deaths have occurred because some practitioners chose not to use these auxiliary labels. Intrathecal medications should always be dispensed in sterile over wraps that can be easily distinguished from medications dispensed for intravenous administration. Interested readers are strongly encouraged to review the recommendations endorsed by ISMP (www.ismp.org/newsletters/acutecare/articles/20051201.asp), the Joint Commission (www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_34.htm), and the World Health Organization (www.who.int/medicines/publications/drugalerts/Alert_115_vincristine.pdf)

Nexium® Dispensed Instead of Nexavar®

A patient with unresectable hepatocellular carcinoma had an order written for Nexavar (sorafenib). The pharmacist misinterpreted the order as Nexium (esomeprazole). In this institution, the pharmacist substituted the misinterpreted Nexium order with Protonix® (pantoprazole). To prevent this error, TALL man letters (nexIUM and nexAVAR) should be used in all medication ordering, dispensing and labeling systems. Oral chemotherapy should also be stored in a separate area of the pharmacy, away from other oral drugs. It would also

have helped if the prescriber listed the clinical indication with the medication order.

Purinethol® Dispensed Instead of Propylthiouracil

A fatal error occurred when a pregnant woman was given a prescription for propylthiouracil, abbreviated as "PTU," but received Purinethol (mercaptopurine) instead. A second patient experienced hepatotoxicity when an order for propylthiouracil written as "PTU" was also dispensed as Purinethol. To prevent this error, the dangerous abbreviation "PTU" should never be used. As suggested by ISMP, no abbreviations should be allowed when prescribing any medication. Furthermore, prescribers should list a clinical indication when prescribing these drugs. Lastly, pharmacies should not store propylthiouracil and Purinethol near one another and seriously consider using "name alert" warning labels on product containers.

Serious Neuropsychiatric Adverse Events Associated with Varenicline (Chantix®)

This drug, used in cigarette smoking cessation programs, is responsible for an increasing number of deaths. The FDA-approved medication guide should be distributed to all patients starting therapy with this agent. See www.fda.gov/cder/drug/infopage/varenicline/default.htm and www.ismp.org/docs/vareniclineStudy.asp for more information. ■

HOPA E-Alerts: A Gateway to Oncology Resources

Karl Kwok, PharmD, HOPA Publications Committee

The HOPA website [Resources](#) section contains links to a variety of materials that may be helpful to your practice. You can start by clicking [E-Alerts](#) under the **Resources** tab, where you can view "best practice" links to ASCO VTE & ESA guidelines and NCCN Clinical Practice Guidelines. The E-Alerts page also provides links to clinical pearls, journal articles, legislative news, and the ongoing feature "FDA Approvals & News." You can also view E-Alerts and drug updates from past newsletters. The **Resources** page also has valuable information and tools, including links for complementary and alternative medicine, clinical trials, governmental organization tools, and even job listings. Try it out and let the Publications Committee know what you think!

HOPA MEMBERSHIP SURVEY, AUGUST 2008

HOPA conducted a survey of its members from August 14 to August 28, 2008. Several different HOPA committees contributed questions to the survey, so this was a joint effort to poll our membership on many different issues. Thank you to all of you who took the time to go through the survey; an impressive 272 members responded!

(CONTINUED ON PAGE 10)

COMMITTEE UPDATES

Update from the HOPA Board

Cindy L. O'Bryant, President

Well, another top-quality annual meeting is behind us. The HOPA Board again wants to thank all HOPA and ISOPP members who attended and made this meeting so successful. Planning for the [HOPA 5th Annual Meeting](#), to be held June 17-20, 2009, at the Doral Marriott in Miami, Florida, is underway.

The main focus of HOPA this year is the implementation of our new strategic plan for HOPA's future (available to members at www.hoparx.org/MembersOnly.aspx; you will need to be logged in). We are off to a great start with HOPA University (www.hopaU.org) now up and running. The purpose of this website is to provide you with HOPA-sponsored educational opportunities that will enhance your practice. If you have not taken a look at the website I encourage you to do so. Currently there are seven educational programs available and the development of new programming is ongoing.

As you will see below, the committees are working hard to make all aspects of the strategic plan a reality. I thank all those on a committee for their commitment and effort. There is so much to do that many of the committees will be creating *ad hoc* task forces to help with the work. So, if you are not on a committee but would like to help, be looking for opportunities to serve on one of these task forces. Additionally, as we move forward with the strategic plan you may receive a number of surveys from the different committees. These surveys will provide each committee with valuable information needed to accomplish assigned objectives within the strategic plan. Please take the time to fill out each survey as your input is valuable to the creation of programs that benefit membership.

With the amazing growth HOPA has seen over the last few years the time has come to revise the organization By-Laws. The By-Laws are important to the administrative function of HOPA. Members were sent an e-mail in October with proposed revisions to the By-Laws; thank you to all the members who reviewed the revisions and provided comments. The Board will be reviewing your comments and making the appropriate revisions, and depending on the extent of the suggestions/revisions the Board will either be requesting a vote to approve revisions or allowing more time for comments from the membership. Please keep an eye out for these important e-mails. The final step will be sending the By-Laws out for a member vote on approval.

Lastly, the HOPA Board hears your concerns and is sensitive to issues that pertain to you and your practice. The board met in Dallas in November to discuss important issues currently facing the organization and membership.

CE Accreditation Committee

Chair, LeAnne Kennedy • Vice-Chair, Janet Espirito • Board Liaison, Cindy O'Bryant

Getting ready for the annual meeting is the busiest time for our committee. Last year we reviewed over 70 presentations for ACPE credit, ensuring both the accuracy of the presentations and representation of fair balance. We are pleased to announce that HOPA issued over 6,850 hours of continuing education for the HOPA 2007 meeting and over 6,500 hours of credit (so far) for the HOPA/ISOPP 2008 meeting. Hopefully you were able to take advantage of some of the great educational programming provided in cooperation with the Education & Standards Committee. This year we will continue to work hand in hand with the Education & Standards Committee and the newly created Program Committee.

Introducing HOPA University

[HOPA University](http://www.hopaU.org) (www.hopaU.org), a new website created by the HOPA leadership, brings together all HOPA-sponsored educational activities onto a single platform. You can complete HOPA CE programs on HOPA U as well as access a list of programs you've completed on the site. We hope you find HOPA U a useful and valuable educational tool. Feedback and questions can go to info-hopau@hopau.org.

Seven educational programs are now available on HOPA U. Five of these programs are based on lectures at the HOPA/ISOPP meeting in Anaheim. *Please note that those who claimed CE credit for the live version of these programs are ineligible to claim credit for the online activities.*

1. [Integrating the Epothilones into Clinical Practice: Focus On Breast Cancer](#)
2. [Optimizing Patient Adherence to Self-Administered Chemotherapy: Best Practices for Hematology/Oncology Pharmacists](#)
3. [Targeted Drug Therapies for the Treatment of Non-Small-Cell Lung Cancer](#)
4. [Updates in Cancer Supportive Care: Venous Thromboembolism, Tumor Lysis Syndrome, and Chemotherapy-Induced Nausea and Vomiting](#)
5. [What's New in the Management of Multiple Myeloma?](#)
6. [Taking Aim at Multiple Targets: Oncology Pharmacist Perspectives on TKIs](#)
This activity is based on a live program at HOPA 2007 in Denver.
7. [New Directions in Metastatic Renal Cell Carcinoma](#)
This original activity is not based on a previous live program.

Education & Standards Committee

Chair, Sally Barbour • Vice-Chair, Sarah Scarpace • Board Liaison, Phil Johnson

The Education & Standards Committee has been busy since the 2008 annual meeting. We have a great committee of practitioners with diverse areas of specialty within oncology pharmacy and a varied level of experience. We are excited to have launched HOPA U with several enduring educational activities from the annual meeting. In addition, we are busy developing ideas for new programs for HOPA U. So that we best meet the needs of our membership, we sent out a survey in October to all HOPA members to gather feedback on educational needs and interests, preferred learning methods, best practices, and interest in training tools. In addition to education, one of the main goals of this committee is to develop HOPA oncology practice standards. It is our goal to begin development on two practice standards—one clinically focused and one technically focused—with the actual topics chosen by the membership. We are excited about all the work we have done, the diverse educational opportunities that are in development, and the ongoing creation of HOPA's first set of practice standards.

COMMITTEE UPDATES

(CONTINUED)

Legislative Affairs Committee

Chair, Niesha Griffith • Vice-Chair, Steve Fijalka • Board Liaison, Phil Johnson

CMS Releases Guidance on Use of Drug Compendia

On October 24, 2008, the Centers for Medicare & Medicaid Services (CMS) released a Change Request (CR) regarding three newly recognized drug compendia and how information from them should be interpreted. The list of compendia recognized by CMS was changed recently to include three new compendia in addition to the already recognized American Hospital Formulary Service *Drug Information (AHFS-DI)* published by ASHP; the NCCN's *Drugs & Biologics Compendium™*, Thomson Micromedex's *DrugDex®*, and Elsevier Gold Standard's *Clinical Pharmacology*. The four nationally recognized drug compendia are authoritative drug reference books that include information about off-label indications, particularly with regard to cancer drugs.

The CR instructs contractors to accept indications that:

- are favorably listed in one or more of the approved compendia or
- the contractor determines from a review of the peer-reviewed literature that it is a medically accepted indication, unless CMS has determined that the use is not medically accepted, or any of the recognized compendia list the use as not medically accepted.

"Medically accepted indications" are those in which: 1) the indication is a Category 1 or 2A in the *Drugs & Biologics Compendium*, or Class I, Class IIa, or Class IIb in *DrugDex*; or, 2) the narrative text is supportive in *AHFS-DI* or *Clinical Pharmacology*. A use is not medically accepted if the 1) indication is a Category 3 in the NCCN compendium or a Class III in *DrugDex*; or, 2) the narrative text in *AHFS-DI* or *Clinical Pharmacology* is "not supportive." The CR does not mention Category 2B listings from the NCCN compendium in either the accepted or non-accepted category. It is likely, therefore, that coverage for a 2B indication will be left to the discretion of the local Medicare contractor.

Legislative Proposal for Medication Therapy Management (MTM) Services Under Medicare Part B

During the ACCP Annual Meeting in Louisville, Kentucky, HOPA members who are also members of the ACCP Hematology/Oncology PRN met with John McGlew, ACCP's Assistant Director of Government and Professional Affairs, to discuss the legislative proposal for expanding MTM services coverage to include coverage under Medicare Part B.

ACCP has taken the lead role in "The Leadership for Medication Management" (LMM), a coalition representing seven national pharmacy organizations (including ASHP, AMCP, etc). The coalition has developed a series of legislative principles aimed at expanding opportunities for pharmacists to provide patient care services to Medicare beneficiaries. LMM works to generate support for these principles and ultimately secure sponsors to introduce legislation based on the principles. A full version of the principles is available at <http://www.accp.com/docs/govt/advocacy/Leadership%20for%20Medication%20Management%20-%20Legislative%20Principles.pdf>, but under this legislative proposal, all Medicare Part D beneficiaries would have access to one annual medication review. In addition, all Medicare beneficiaries, whether or not they participate in Part D, would have access to MTM services under Medicare Part B, utilizing the applicable CPT codes for pharmacist-provided MTM services. HOPA members are encouraged to contact their members of Congress and educate them regarding the benefits of clinical oncology

pharmacy services. Inviting them to visit your practice site to see firsthand the positive impact an oncology pharmacist can have on patient care is one of the best ways to do that.

The Legislative Committee will continue to monitor and report on the progress of this legislative proposal, consider the possibility of joining the coalition, and provide their recommendations to the HOPA Board.

BCOP Recertification Committee

Chair, Casey Williams • Vice-Chair, Amy Hatfield Seung • Board Liaison, Jane Pruemmer
Fall and winter continue to be very active times of the year for the BCOP Recertification Committee. The committee has identified six presentation topics for the "live" portion of the 2009 recertification cycle and invited speakers for the three meetings on its calendar. The committee is responsible for the six recertification hours provided at the HOPA Annual Meeting, which is repeated at the ACCP Annual Meeting and at the ASHP Midyear Meeting. The committee is also working collaboratively with both ACCP and ASHP to create and implement a standard procedure for validating recertification test questions. The goal of this endeavor is to have a formalized process that all three organizations will use to validate the questions used for BCOP Recertification assessments for the home syllabus, the review course, and the "live" sessions. Lastly, the committee continues to work with our meetings management and organizational partner, DesignWrite, to secure financial support for the 2009 programming.

Nominations & Awards Committee

Chair, Michelle Rockey • Vice-Chair, Susanne Liewer • Board Liaison, Jane Pruemmer
The Nominations & Awards Committee has expanded its membership to 9 members. The committee welcomes new members Val Adams, Julianna Roddy, and Laura Jung. This Fall the committee was very busy soliciting nominations for the 2009 HOPA Recognition Awards. The award winners will be presented at the annual conference in June 2009.

Our next mission is setting the slate for the Executive Board elections. The call for nominations for the HOPA Executive Board will open in January. The Executive Board has recommended revising the By-Laws to expand the number of Member-at-Large positions. If the revised By-Laws are approved, the Board will have a total of 3 Member-at-Large positions in 2009 and 4 positions in 2010. Start thinking about who you would like to nominate for the President-Elect, Secretary, and two Member-at-Large positions! The elections will open in March.

Membership Committee

Chair, Alex Kardos • Co-Chair, Stephanie Sutphin • Board Liaison, Lisa Holle
Data from the end of October 2008 show that HOPA has set a new record for membership, with 1,212 members. This is an increase of 26.8% from October of 2007 (956 members), far exceeding the Committee's goal of increasing membership by 10% per year.

The Committee has been focused on ways to continue to increase membership both by recruiting new members and retaining current members. We are currently discussing the formation of focus groups to target specific groups in the pharmacy community that may be underrepresented in the current membership, such as technicians and community-based pharmacists. Based on response data from the Membership Survey we have also discussed the possibility of offering extended-cycle memberships and/or automatic membership renewal, changing the renewal notice timetable for current members, and changing the membership cycle. ■

ERYTHROPOIETIN-STIMULATING AGENTS

Changes in the Management of Chemotherapy-Induced Anemia: Where Are We Now?

Stacy S. Shord, PharmD, BCOP, University of Illinois at Chicago

Anemia is a common side effect observed in about 65% of patients receiving myelosuppressive chemotherapy.^{1,2} Transfusions were the cornerstone of management of anemia in patients with cancer until the approval of the labeling of recombinant form of the erythropoietin hormone (epoetin alfa, Procrit®, Ortho Biotech) for chemotherapy-induced anemia (CIA) by the FDA in 1991.³ The availability of this product revolutionized the treatment of CIA, especially in light of the heightened fear of the risks of transmission of infectious agents from the blood supply at the time. A second recombinant form (darbepoetin alfa, Aranesp®, Amgen) was introduced in 2001.⁴ This approval was quickly followed by the development of clinical practice guidelines by the American Society of Clinical Oncology (ASCO) and the American Society of Hematology (ASH) in 2002.⁵

These erythropoietin-stimulating agents (ESAs) became the standard of care for the treatment of CIA and minimized the need for red blood cell transfusions, reducing the mean incidence of transfusions from 44% to 25%.^{2,6-12} Other outcome measures included changes in hemoglobin (Hb) concentrations and quality of life measures, but it has not been proven that targeting a specific Hb concentration improves quality of life. Four head-to-head comparisons of ESAs demonstrated similar therapeutic efficacy based on changes in Hb concentrations.¹³⁻¹⁶ The initial clinical practice guidelines supported starting treatment when the Hb was less than 10 g/dL and a target Hb of 12 g/dL.⁵ Two other studies supported improved outcomes with earlier initiation; that is starting ESAs when the Hb was less than 11 g/dL.^{17,18} Few adverse events were reported and the benefits appeared to far outweigh the risks associated with transfusions.

Following clinical reports describing the risks for tumor promotion and increased mortality in patients with cancer, the Oncologic Drug Advisory Committee (ODAC) convened in May 2004 to review the safety of these agents. These reports focused on two clinical studies (BEST and ENHANCE) that suggested ESAs decreased survival in patients with either breast or head & neck cancers. The committee members proposed design elements for future studies to address the safety concerns of these agents. Warnings and precautions were subsequently added to

the product labeling to include a description of these studies and highlight the risks for tumor progression and death. The FDA subsequently published three health advisories regarding the safety of these agents.

Three years after the ODAC meeting in 2004, the committee members reconvened and concluded the safety concerns were not adequately addressed in the clinical trials conducted to date. An increased risk of venous thromboembolism was readily apparent, but it was still unclear whether these agents were associated with an increased risk of tumor progression or mortality. Additional changes were made to the product labeling in March 2007. The revisions included updated warnings, a new boxed warning, and modifications to the dosing instructions. The boxed warning included a statement that the lowest ESA dose that will gradually increase the Hb level to a concentration sufficient to avoid the need for blood transfusions should be used. Furthermore, the Centers for Medicare and Medicaid Services (CMS) issued a National Coverage Decision in July 2007 that redefined CIA and restricted the reimbursement of these agents to patients with Hb less than 10 g/dL.

The ODAC reconvened again in March 2008 to further examine the survival data and the safety of ESAs. At this point in time, eight studies illustrated an increase in tumor progression or a decrease in survival. Two studies were conducted in patients not receiving chemotherapy, two studies were conducted in patients receiving radiotherapy, and four studies were conducted in patients receiving chemotherapy.¹⁹ The common thread in these studies was that the patients had received these agents outside of the initial labeling. Specifically, the target Hb in these studies exceeded the initial recommendation of a target Hb of 12 g/dL. With some meta-analyses demonstrating an increased risk of mortality with a hazard ratio slightly greater than one,^{17,20,21} the decreased survival observed in the eight studies may be "real." What remains uncertain is whether survival is compromised in patients receiving ESAs within the initial labeling. The most recent revisions to the product information issued in August 2008 state that ESAs are no longer indicated for patients receiving myelosuppressive therapy when the anticipated outcome is cure, and the patient package insert

(CONTINUED ON PAGE 5)

FDA NEWS

Kim Bergstrom

HOPA Publications Committee

Bendamustine Receives Approval in Indolent B-cell NHL

Bendamustine hydrochloride (Treanda®, Cephalon, Inc.) has been approved by the FDA for the treatment of patients with indolent B-cell non-Hodgkin's lymphoma (NHL) that has progressed during or within 6 months of treatment with rituximab or a rituximab-containing regimen. Bendamustine received FDA approval earlier this year for the treatment of chronic lymphocytic leukemia. This most recent approval is based upon data from a study of 100 patients with indolent B-cell NHL who had progressed on rituximab therapy; the study showed an overall response rate with bendamustine of 74% and a median duration of response of 9.2 months. Disease progression was delayed by a median of 9.3 months.

Non-hematologic adverse reactions occurring in >15% of patients included nausea, fatigue, vomiting, diarrhea, pyrexia, constipation, anorexia, cough, headache, weight loss, dyspnea, rash and stomatitis. The most common hematologic toxicities are lymphopenia, leukopenia, anemia, thrombocytopenia and neutropenia, again occurring in >15% of patients.

Bendamustine has clearly demonstrated the ability to provide a durable response in patients with indolent B-cell NHL with a tolerable safety profile. Bendamustine now provides a convenient treatment option because it is a 60 minute infusion given in the outpatient setting.

Reference

1. Cephalon Receives FDA Approval for TREANDA to Treat Patients with Relapsed Indolent Non-Hodgkin's Lymphoma [press release]. Frazier, PA: PRNewswire-FirstCall; October 31, 2008. Available at: www.cephalon.com/media/news-releases/article/cephalon-receives-fda-approval-for-treanda-to-treat-patients-with-relapsed-indolent-non-hodgkins-ly. Accessed 11/3/08.

Denileukin Diftitox Receives FDA Approval in Patients with CTCL

The FDA has approved a supplemental biologics license application (sBLA) for denileukin diftitox (Ontak®, Eisai Corporation) for use in patients with persistent or recurrent CD25+ cutaneous T-cell lymphoma (CTCL). A separate efficacy supplement that included data from patients with CTCL whose malignant cells were not CD25-positive received a complete response letter. This approval was based on data

(CONTINUED ON PAGE 5)

ERYTHROPOIETIN-STIMULATING AGENTS

(continued from page 4)

was replaced with a medication guide. Previous revisions to the labeling were also changed to clarify that ESAs should not be started when Hb \geq 10 g/dL and that the target Hb is the lowest Hb level needed to avoid transfusions. The boxed warning focused on the studies in which the target Hb was $>$ 12 g/dL, which were also removed from the revised labeling. Finally, the FDA required that manufacturers replace the patient package insert with an FDA-approved patient "Medication Guide." Under FDA regulations, this Medication Guide must be given to patients when the drug is dispensed (as opposed to a patient package insert, which is voluntarily distributed). Furthermore, although Medication Guides are usually only required for use outside of a physician office or hospital, in rare instances, the FDA requires distribution of the Medication Guide to all patients. At this time it is unclear whether the FDA mandates distribution to all patients.

How has this sequence of events changed prescribing patterns? The number of patients receiving ESAs has dramatically declined. Today, only patients with metastatic disease are now offered these agents; but an undocumented number of patients are declining ESAs after reading the Medication Guide. Consequently, the number of patients receiving a transfusion has risen.²² A recent model presented by Dr. Lefebvre at the 2008 Society for the Advancement of Blood Management annual meeting indicates that a 25% decrease in the use of ESAs will lead to a 10% to 32% increase in demand for red blood cells. It appears once again that transfusions may be the standard of care for CIA. Dr. Lefebvre further states that the increase in transfusions will impose considerable pressure on the blood supply in the US. Another concern centers on several studies that demonstrate increased morbidity and mortality following transfusions in patients with cancer; interestingly, the impact on survival may be related to storage duration or conditions of the red blood cells.^{23,24} Other lingering concerns include a risk of transfusion reactions and immunosuppression. Overall, it appears that both treatment options, transfusions and ESAs, may be associated with devastating risks. Additional, appropriately designed studies are needed to define the impact of these agents on survival in patients receiving chemotherapy for curative and palliative intent within the previously defined target Hb, as well as the potential impact of transfusions on survival. These studies will take several years to complete leaving us with no resolution in regards to how to treat patients now.

Moreover, the role of iron also needs to be defined in this patient population. Five clinical studies indicated that intravenous iron improves hematopoietic response when administered in combination with ESAs.²⁵⁻²⁹ Furthermore, parenteral iron can reduce the dose of ESAs and further minimize the need for transfusions. Most notably, the improvements in hematopoietic response were irrespective of baseline iron availability or stores. The major concern with intravenous iron stems from a perceived risk of allergic reactions; but these reactions are limited to a high-molecular-weight iron dextran formulation, which should be not be administered to patients in light of the markedly reduced risk of these reactions with other intravenous iron preparations.^{30,31} It is estimated that 60% of patients with cancer are iron deficient and 80% of these patients have relative iron deficiency, indicating their inability to use the iron within their bodies to make red blood cells, supporting a need for intravenous iron in patients with cancer.³² It is unknown at this time whether intravenous iron administered in conjunction with ESAs can minimize the impact of these agents on survival and whether intravenous iron alone can reduce the need for transfusions for patients with cancer.

(CONTINUED ON PAGE 6)

FDA NEWS (continued from page 4)

from the largest phase III randomized, double-blind, placebo-controlled study ever conducted in CTCL.

Patients (n=144) were randomized to receive one of two doses of denileukin diftitox (18 mcg/kg/day or 9 mcg/kg/day) or placebo by intravenous infusion on days 1–5 every 21 days for up to 8 cycles. Approximately 67% of the patients had stage IIa or lower disease whereas 33% had stage IIb or III. The primary endpoint was overall response rate (ORR) while secondary endpoints included progression-free survival (PFS) and safety. Response rates for the 18 mcg/kg and the 9 mcg/kg groups were 46% and 37%, which were both significantly higher than placebo (15%, $p=0.002$ and $p=0.03$, respectively). Moreover, the 18 mcg/kg group demonstrated a 73% reduction in the risk of disease progression ($p=0.0002$) while the 9 mcg/kg group showed a 58% reduction in the risk of disease progression ($p=0.02$).

Serious adverse events occurred in 25% of patients treated with denileukin diftitox and included capillary leak syndrome (4%), dehydration (4%), pyrexia (3%), hypotension (2%), skin disorder (2%), chest pain (2%), hypoalbuminemia (2%) and fatigue (2%). Adverse events occurring in more than 10% of denileukin diftitox-treated patients are listed below.

Denileukin Diftitox vs Placebo in CTCL: Summary of Phase III Safety Results

	Denileukin Diftitox 18 mcg/kg	Denileukin Diftitox 9 mcg/kg	Placebo
Pyrexia, %	63.6	48.9	15.9
Nausea, %	60	46.7	22.7
Rigors, %	47.3	42.2	20.5
Fatigue, %	43.6	46.7	31.8
Vomiting, %	34.5	13.3	6.8
Headache, %	25.5	28.9	18.2
Peripheral edema, %	25.5	20	22.7
Diarrhea, %	21.8	22.2	9.1
Anorexia, %	20	8.9	4.5
Rash, %	20	24.4	4.5
Myalgias, %	20	17.8	4.5
Cough, %	18.2	20	6.8
Pruritus, %	18.2	15.6	9.1
Back pain, %	18.2	15.6	2.3
Asthenia, %	18.2	17.8	4.5
Hypotension, %	16.4	6.7	2.3
URI, %	12.7	13.3	11.4
Dizziness, %	12.7	11.1	11.4
Arthralgias, %	12.7	15.6	11.4
Chest pain, %	12.7	4.4	2.3
Dysgeusia, %	10.9	0	2.3
Dyspnea, %	10.9	13.3	4.5

URI = upper respiratory infection

Reference

2. FDA Grants Full Approval to ONTAK(R) (denileukin diftitox) for Use in Patients with Cutaneous T-Cell Lymphoma (CTCL) [press release]. Woodcliff Lake, NJ: PRNewswire; October 15, 2008. Available at http://www.prnewswire.com/cgi-bin/stories.pl?ACCT=ind_focus.story&STORY=/www/story/10-15-2008/0004905110&EDATE=WED+Oct+15+2008,+10:49+PM. Accessed 11/25/08. ■

For more FDA News, visit www.hoparx.org/EAlerts.aspx

ERYTHROPOIETIN-STIMULATING AGENTS (continued from page 5)

In summary, the management of CIA has undergone dramatic changes in the past two decades following the emergence of the ESAs. Transfusions once again appear to be the standard of care for most patients with CIA in light of the revised labeling and patient refusals. However, recent concerns regarding the hidden risks associated with transfusions suggest that the recent increase in transfusions as a means to treat CIA in place of ESAs may not provide the improved long-term outcomes we desire. Questions remain regarding the relative safety of the ESAs when prescribed within the prior approved indications of target Hb of 12 g/dL, the uncertainty of the availability of the blood supply to meet the increased demands and the potential impact of transfusions on survival. Furthermore, the role of intravenous iron with and without ESAs needs to be the focus of future clinical studies. ■

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DRUG UPDATES

BENDAMUSTINE (Treanda®)

Class: Antineoplastic/alkylating agent/antimetabolite

Indication: Treatment of chronic lymphocytic leukemia (CLL)

Off-label use: Treatment of non-Hodgkin's lymphoma (NHL)

Dose: CLL (adults): 100 mg/m² IV on days 1 and 2 of a 28-day treatment cycle (for up to 6 cycles)

Dose adjustments: Necessary for renal dysfunction, moderate to severe hepatic impairment, and ≥grade 3 hematologic or non-hematologic toxicities

Adverse effects: Bone marrow suppression, dermatologic toxicity, hypersensitivity/infusion reaction, tumor lysis syndrome, nausea, vomiting, increased LFTs.

Drug interactions: CYP1A2 inducers or inhibitors

Bendamustine in Chronic Lymphocytic Leukemia

*Christopher Thomas, PharmD
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Chronic lymphocytic leukemia (CLL) is the most prevalent lymphoproliferative disorder in the Western hemisphere primarily affecting adults, especially the elderly.^{3,4} Although a large population is affected by the diagnosis of CLL, many patients never require pharmacologic treatment.⁷ Patients may remain stable without clinical deterioration for many years, whereas others may present with more advanced stages, necessitating immediate treatment. Patients presenting with more advanced disease are in need of highly effective antineoplastic treatment regimens that will facilitate their ability to achieve complete remission.

Historically, alkylating agents have been first-line agents for CLL patients requiring treatment, with cyclophosphamide and chlorambucil being the most commonly used. Purine analogs, such as fludarabine, are also used alone or in combination for CLL.⁷ A new agent, bendamustine (Treanda®, Cephalon), was approved in March 2008 for the treatment of chronic lymphocytic leukemia.²

(CONTINUED ON PAGE 8)

ROMIPILOSTIM (Nplate™)

Class: Hematopoietic – thrombopoiesis-stimulating peptibody

Indications: Adults (≥18 years) with chronic immune thrombocytopenia purpura (ITP) who are unresponsive to treatment with corticosteroids, immunoglobulin, or splenectomy, or whose thrombocytopenia puts them at a greater risk for bleeding.

Dose: Initial: 1 mcg/kg subcutaneously once weekly, adjust dose weekly in increments of 1 mcg/kg to achieve platelet count of 50 x 10⁹/L or greater; maximum weekly dose 10 mcg/kg. If the platelet count is not adequate to control bleeding after 4 weeks of therapy on the maximum dose, discontinue therapy and continue monitoring platelets for 2 weeks

Adverse effects: Bleeding, abdominal pain, diarrhea, nausea, arthralgia, headache, epistaxis, fatigue

Romiplostim in Immune Thrombocytopenia Purpura

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Immune thrombocytopenia purpura (ITP) is an acquired immune disorder characterized by thrombocytopenia where other causes have been excluded. Platelet production is decreased and platelet destruction is increased in patients with ITP.¹ In ITP, platelets are labeled with IgG autoantibodies. The platelets then undergo increased clearance through Fcγ receptors on macrophages.² This commonly occurs in the spleen. There are differences in adults and children with ITP. Children often present with sudden onset of petechiae or purpura, which commonly occurs after an infectious illness. ITP in children often resolves within about 6 months with or without treatment.² ITP in adults is commonly a chronic disease.² ITP is diagnosed by exclusion of other causes of thrombocytopenia. Adults typically require treatment upon diagnosis, whereas the decision to initially treat children is controversial. If treatment is required for a child, it is recommended to use the lowest amount of therapy needed for a response.² Typically, adult patients who present with a platelet count >50 x 10⁹/L do not require treatment unless the

(CONTINUED ON PAGE 8)

GRANISETRON TRANSDERMAL SYSTEM (Sancuso®)

Class: Serotonin 5-HT₃ receptor antagonist

Indication: Prevention of nausea and vomiting in patients receiving moderately and/or highly emetogenic chemotherapy for up to 5 consecutive days

How supplied: In individual foil pouches, with each 52 cm² patch containing 34.3 mg of granisetron

Dose: Granisetron is released at a rate of 3.1 mg per 24 hours, for up to 7 days

Directions for use: Apply a single transdermal system (patch) to the upper outer arm a minimum of 24 hours before chemotherapy. The patch can be worn up to 7 days depending on the duration of the chemotherapy regimen.

Dose adjustments: None required

Common adverse effects: Constipation, headache

Drug interactions: No clinically significant drug interactions

Special instructions: The patch should not be cut into pieces

Granisetron Transdermal Patch in CINV

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Granisetron Transdermal System (Sancuso®, ProStrakan) was approved in August 2008. ProStrakan expects to launch Sancuso before the end of 2008 – its first product launch in the US.¹ Granisetron Transdermal System is indicated for the prevention of nausea and vomiting in patients receiving moderately and/or highly emetogenic chemotherapy regimens of up to 5 consecutive days of duration. Sancuso delivers granisetron, an established 5-HT₃ receptor antagonist, steadily into the bloodstream for up to seven days. Serotonin receptors of the 5-HT₃ subtype are located peripherally on vagal nerve terminals and centrally in the chemoreceptor trigger zone in the brain. During chemotherapy, mucosal enterochromaffin cells release serotonin, which stimulates 5-HT₃ receptors. This evokes vagal

(CONTINUED ON PAGE 8)

DRUG UPDATES (CONTINUED)

BENDAMUSTINE (Treanda®)

Like cyclophosphamide and chlorambucil, bendamustine is an alkylating agent of the nitrogen mustard type. Unlike these two, bendamustine is only available in an intravenous formulation and possesses antimetabolite properties (similar to purine analogs) in addition to its role as an alkylating agent.^{1,2,3}

The FDA approval of bendamustine was based on a pivotal trial comparing its efficacy in first-line treatment of CLL to that of chlorambucil.² In this trial, 301 patients with Binet Stage B or C chronic lymphocytic leukemia were randomized to receive either chlorambucil 0.8 mg/kg orally on days 1 and 15 of each 28-day cycle or bendamustine 100 mg/m² given intravenously via a 30-minute infusion on days 1 and 2 of a 28-day cycle. This study revealed a statistically significant difference in response rate, with bendamustine and chlorambucil achieving 90% and 38% overall responses, respectively ($p < 0.0001$). Although the other primary endpoint, progression-free survival, is still being evaluated, bendamustine has shown a 13% complete response rate in comparison to only 1% in patients who received chlorambucil. This is reflected by the separation of Kaplan-Meier curves, which provides an estimate of progression-free survival, after only 3 months of treatment.

Guidelines developed by the National Comprehensive Cancer Network (NCCN) for the treatment of non-Hodgkin's lymphoma were recently updated to include recommendations for the use of bendamustine.⁵ At this time, the NCCN guidelines support the use of bendamustine as first-line therapy for CLL as a single agent, or in combination with rituximab as second-line therapy. Additionally, the guidelines support the use of bendamustine with or without rituximab for the second-line treatment of mantle cell lymphoma, or as second- or subsequent-line therapy for follicular lymphoma.⁵

In addition to use in chronic lymphocytic leukemia, bendamustine has been used to treat non-Hodgkin's lymphoma (NHL), multiple myeloma, breast cancer, and small-cell lung cancer.¹ It has shown promise in phase II clinical trials in patients refractory to treatment

(CONTINUED ON PAGE 9)

ROMIPILOSTIM (Nplate™)

patient is symptomatic or at an increased risk for bleeding; this may include patients with hypertension, peptic ulcer disease, or a vigorous lifestyle.³ Patients presenting with a platelet count of $< 20 \times 10^9/L$ or severe/life threatening bleeding should be hospitalized and treated with one of the pharmacologic agents currently available for the treatment of ITP.³ Initial therapy is prednisone, which has a response rate of 50% to $> 75\%$. Intravenous immune globulin (IVIG) is an agent that can be used to treat patients with ITP who have extensive or increasing purpura despite treatment with steroids.² Patients who do not respond to steroids can be treated with anti-D immune globulin (RhoGAM®, Ortho-Clinical Diagnostics). Splenectomy is reserved for patients with splenic crisis.

Patients with chronic, refractory ITP generally require treatment if platelets fall below $30 \times 10^9/L$.² Three classes of agents are used as treatment for these patients. The first class inhibit platelet clearance and include prednisone, IVIG, vinca alkaloids, and danazol.² The next class are the immunosuppressive agents, such as azathioprine, cyclophosphamide, and cyclosporine. The last class are experimental agents that can be used for patients with refractory ITP. Some of these experimental options include antibodies against CD20 or CD154 and bone marrow transplantation.²

ITP was originally thought to be a benign disease.⁴ In 2000, a study was published that evaluated the bleeding risk and prognosis of patients with ITP that have persistent low platelet counts. In this study, 17 case series that included 1817 patients diagnosed with ITP were examined.⁴ Those with chronically low platelets (less than $30 \times 10^9/L$) were shown to have a decreased life expectancy.⁴ The decrease in life expectancy ranged from a loss of 20 years in patients who were 25 years old to a loss of 9 years in patients who were 70 years old.⁴ These results suggest that patients with persistently low platelets should be treated more aggressively.

Romiplostim (N-Plate™, formerly AMG531, Amgen) is a thrombopoiesis-stimulating peptidomimetic protein recently approved (August 22, 2008) by the FDA for patients with

(CONTINUED ON PAGE 9)

GRANISETRON TRANSDERMAL SYSTEM (Sancuso®)

afferent discharge, inducing vomiting. Animal studies demonstrate that, in binding to 5-HT₃ receptors, granisetron blocks serotonin stimulation and subsequent vomiting after emetogenic stimuli such as chemotherapy.²

Sancuso is the first transdermal 5-HT₃ receptor antagonist product.¹ Sancuso has been shown to be as efficacious as oral granisetron in preventing the side effects of nausea and vomiting in patients undergoing chemotherapy.³ Sancuso has the advantage of offering this protection through a single transdermal patch application, eradicating the need for repeated daily injections, thus reducing potential infection risk, or having to swallow multiple pills on a repeated daily basis, which is often problematic in cancer patients due to mucositis.

Sancuso was FDA approved based on a single multicenter, phase III, randomized, double-blind, parallel group, double-dummy, non-inferiority, controlled study.³ The study compared the efficacy, tolerability and safety of Sancuso to once-daily oral granisetron (2 mg). The population randomized into the trial included 641 patients, 48% males and 52% females aged 16 to 86 years, who received moderately or highly emetic multi-day chemotherapy. The granisetron patch was applied 24 to 48 hours before the first dose of chemotherapy, and kept in place for seven days. The comparator group received oral granisetron 2 mg administered daily for the duration of the chemotherapy regimen, one hour before each dose of chemotherapy.³ The study met its primary endpoint of non-inferiority of complete control of chemotherapy induced nausea and vomiting compared to oral granisetron.³ Complete control was defined as no vomiting and/or retching, no more than mild nausea and no rescue medication from first administration of Sancuso until 24 hours after the last day of chemotherapy. Complete control of nausea and vomiting was established in 60.2% of patients in the Sancuso arm and 64.8% of patients receiving oral granisetron (difference -4.89%; 95% confidence interval -12.91% to +3.13%).³ The most frequent adverse events were constipation (5.4%) and headache (0.7%).² Granisetron may be affected by direct or artificial sunlight. In addition

(CONTINUED ON PAGE 9)

DRUG UPDATES (CONTINUED)

BENDAMUSTINE (Treanda®)

with rituximab⁶ as well as in combination with rituximab for patients with NHL.⁷

Adverse reactions most commonly associated with bendamustine include bone marrow suppression, thrombocytopenia, nausea, vomiting, tumor lysis syndrome, and dermatologic reactions. Patients may also experience infusion-related reactions, hypersensitivity, or an increase in LFTs.

Bendamustine represents progress towards the goal of attaining complete remission for CLL patients with clinical deterioration. Its dual mechanism of action—theoretically making it an alkylating agent and purine analog combination—and modest toxicity profile may propel bendamustine to the forefront of CLL management. Given the encouraging data from preliminary clinical trials and NCCN support, bendamustine can be used as a first-line agent for CLL. Unabridged data analyses of completed trials, in addition to future studies, are needed before bendamustine can be considered the gold standard first-line agent for CLL. ■

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ROMIPILOSTIM (Nplate™)

chronic ITP that is unresponsive to treatment with corticosteroids, immunoglobulin, or splenectomy. Romiplostim increases platelet production by binding to and activating the thrombopoietin receptor.^{5,6} This agent should be reserved for patients with ITP whose thrombocytopenia puts them at a greater risk for bleeding.⁵ The goal of treatment should be to maintain a patient's platelet count above $50 \times 10^9/L$. Romiplostim should not be used to normalize the patient's platelet count, and should not be used in patients with a platelet count above $400 \times 10^9/L$.⁵ Patients may experience worsening of thrombocytopenia upon discontinuation of romiplostim.⁵ The use of romiplostim increases the patient's risk of thrombotic events and hematological malignancies.⁵ Complete blood counts, platelet counts, and peripheral blood smears should be monitored weekly in patients on romiplostim until platelet counts reach $50 \times 10^9/L$ or greater, and monthly thereafter.⁵

The efficacy of romiplostim was evaluated in two parallel, prospective, randomized, double-blind, placebo-controlled trials. Romiplostim or placebo was randomly assigned to 63 splenectomized and 62 non-splenectomized patients with ITP.⁶ Adult patients >18 years of age were included if they had a pre-study platelet count of $30 \times 10^9/L$ or less and normal baseline liver and kidney function.⁶ The initial dose was 1 mcg/kg. Previous studies demonstrated a dose-dependant increase in platelet counts; as such, doses were adjusted via a nomogram over the course of the 24-week treatment period to maintain platelet counts of 50 to $200 \times 10^9/L$.^{6,7} Durable platelet response was defined as a platelet count greater than $50 \times 10^9/L$ for at least 6 of the last 8 weeks of treatment.⁶ Transient platelet response was defined as any weekly platelet count greater than $50 \times 10^9/L$ for any 4 weeks during the treatment period.⁶ In the study evaluating non-splenectomized patients, 88% of patients given romiplostim had an overall platelet response (durable or transient) compared with 14% of patients receiving placebo ($p < 0.0001$).⁶ In the study evaluating splenectomized patients, 79% of those receiving romiplostim had an overall platelet response compared to 0% of patients receiving placebo ($p < 0.0001$).⁶ Twenty of twenty-

(CONTINUED ON PAGE 10)

GRANISETRON TRANSDERMAL SYSTEM (Sancuso®)

patients must be advised to cover the patch application site, e.g. with clothing, if there is a risk of exposure to sunlight throughout the period of wear and for 10 days following patch removal because of a potential skin reaction.²

Following a 7-day application of Sancuso in 24 healthy subjects, high inter-subject variability in systemic exposure was observed. Maximal concentration was reached at approximately 48 hours (range 24-168 hours) following patch application. Mean C_{max} was 5.0 ng/mL and mean $AUC_{0-168hr}$ was 527 ng-hr/mL. Based on the measure of residual content of the patch after removal, approximately 66% (SD±10.9) of granisetron is delivered following patch application for 7 days.²

Additionally, an assessment of patch adhesion in 621 patients receiving either active or placebo patches showed that <1% of patches became detached over the course of the 7 day period of patch application.² As a part of the approval, the company has agreed to conduct post-approval clinical studies, including evaluations in children and the elderly.¹ ■

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DRUG UPDATES (CONTINUED)

ROMIPILOSTIM (Nplate™)

three patients on romiplostim reduced or discontinued, compared with only 6 of 16 patients on placebo. In both studies adverse effects were similar in treatment group and placebo group.⁶ The study investigators concluded that romiplostim increased platelet count in both non-splenectomized and splenectomized patients and was well tolerated.⁶

Romiplostim is only available through the restricted NEXUS distribution program (Network of Experts Understanding and Supporting Nplate and Patients).⁸ This program was established to improve physician education, patient safety, and quality of care. Institutions and individual prescribers must enroll in the program in order to prescribe romiplostim.⁸ Each individual patient must separately be enrolled in the program as well. Once the enrollment process is complete, the prescriber has 30 days to complete a baseline data form to provide baseline information about the patient to NEXUS prior to starting romiplostim.⁸ The program requires that patients are given a medication guide that discusses the risks and benefits of romiplostim.⁸ Additionally, patients are required to carry a patient identification card with a dosing tracker that contains the patient's NEXUS access number. Physicians are required to promptly report any adverse events related to romiplostim. The physician can authorize only 6 months of treatment at a time. After 6 months, the patient must be evaluated by the physician. If the decision is made to continue romiplostim, the physician can authorize another 6 months.⁸ The NEXUS program must be notified when the patient discontinues treatment. The NEXUS program also provides physicians and patients with additional resources to ensure the safe use of romiplostim. Additional information about the NEXUS program and information about enrollment can be found at www.nplatenexus.com.

In summary, romiplostim is an agent recently approved by the FDA for treatment of chronic ITP. This agent is an option for patients with ITP who are unresponsive to treatment with corticosteroids, immunoglobulin, or splenectomy, or whose thrombocytopenia puts them at a greater risk for bleeding. If the decision is made to treat a patient with romiplostim, the institution, physician, and patient must enroll in the NEXUS program. ■

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HOPA MEMBERSHIP SURVEY, AUGUST 2008 (CONTINUED)

The survey responses are being reviewed by the HOPA committees, who will use the information to plan new programs and activities that will help keep us the top hematology/oncology pharmacy organization in the US. For example, the Membership Committee is exploring a spring 2010 Annual Meeting (ie, March instead of June) and offering extended membership cycles based on the response from our members. Keep an eye out for additional information about changes based on the results of this survey in future issues of *HOPA News*.

Again, the Membership Committee and HOPA Board would like to thank you for responding to this survey and providing your invaluable suggestions.

The Results

1. What type of HOPA membership do you have?	Response % (n = 272)
Full member	92.3%
Resident	5.9%
Fellow	1.5%
Student	0.0%
Technician	0.0%
Associate member (please specify type of healthcare professional)	0.4%
<i>Answers: pharmacist; fellow; resident</i>	

2. What is your practice site? (please check all that apply)	Response % (n = 270)
Office	3.7%
Medical Office	7.8%
For profit	3.7%
Not for profit	18.1%
Government/military owned	9.3%
Outpatient infusion center	42.2%
Inpatient hospital	47.4%

HOPA MEMBERSHIP SURVEY, AUGUST 2008 (CONTINUED)

Academic affiliation	35.9%
Industry	2.2%
GPO	0.0%
Distribution	0.4%
Other (please specify):	6.7%
<i>Answers: Comprehensive cancer center; Specialty/oral oncology; Outpatient clinic; NHS cancer centre; Consulting for private practice; Ambulatory BMT clinic; Clinic; HMO; Medical publishing; Consulting; Healthcare services company; Medical education; Inpatient hospital and outpatient issues and outreach sites; Inpatient hospital with outpatient clinic; Outpatient clinic; Outpatient infusion center; Ambulatory oncology; Medical communications</i>	
3. How much of your practice/organization is devoted to Hematology/Oncology?	Response % (n = 270)
None	0.4%
1-20%	4.8%
21-40%	5.9%
41-60%	4.8%
61-80%	7.8%
81-99%	20.7%
100%	55.6%
4. How much of your time at your job is spent processing/preparing chemotherapy for dispensing?	Response % (n = 269)
None	31.6%
1-20%	25.3%
21-40%	14.1%
41-60%	11.2%
61-80%	9.7%
81-99%	7.1%
100%	1.1%
5. How much of your time at your job is spent in direct patient care activities?	Response % (n = 268)
None	9.3%
1-20%	28.0%
21-40%	19.4%
41-60%	12.7%
61-80%	15.7%
81-99%	11.9%
100%	3.0%
6. How much of your time at your job is spent conducting administrative activities?	Response % (n = 268)
None	11.6%
1-20%	53.4%
21-40%	17.2%
41-60%	7.1%
61-80%	5.6%
81-99%	4.1%
100%	1.1%

7. How much of your time at your job is spent participating in research activities?	Response % (n = 269)
None	19.0%
1-20%	61.7%
21-40%	10.8%
41-60%	1.5%
61-80%	3.0%
81-99%	2.2%
100%	1.9%
8. How much of your time at your job is spent conducting educational or teaching activities?	Response % (n = 271)
None	6.6%
1-20%	63.8%
21-40%	21.4%
41-60%	6.6%
61-80%	0.7%
81-99%	0.4%
100%	0.4%
9. How did you renew your current HOPA membership?	Response % (n = 271)
Online	83.4%
Mailed application to HOPA	5.9%
Faxed application to HOPA	0.4%
Called HOPA	1.1%
I do not know, my practice site arranged the membership	5.2%
Other (please specify):	4.1%
<i>Answers: Don't remember; Faxed with SWOPs group; Haven't renewed; Paid full price for HOPA 2008</i>	
10. Did you find the process to join or renew your HOPA membership user-friendly?	Response % (n = 270)
Yes	92.2%
Done by practice site	4.4%
No (please explain):	3.3%
<i>Answers: Logging in was a challenge, and then had to find the form to print. E-mail reminder should have a direct link to the form (no login required); I received nothing to indicate I was a new member I when sent in my application (2); Continued to receive calls after renewing membership that membership was out of date, was unable to login to the website. Took multiple calls to resolve; I was unable to locate my online profile even after setting up multiple times; No direction for telephone number formats, took a few attempts to guess how to enter on the form; Had to call and didn't get a prompt response—e-mail questions not answered timely either.</i>	
11. Would you be interested in an extended membership option (paying upfront for multiple years at a discounted rate)?	Response % (n = 270)
Yes, a 2 year membership	44.8%
Yes, a 3 year membership	28.5%
No	22.6%
Other	4.1%
<i>Answers: Discount would have to be >10%; Would be interested in a retired membership if available; Depends on discount.</i>	

HOPA MEMBERSHIP SURVEY, AUGUST 2008 (CONTINUED)

12. Would you be interested in an automatic membership renewal option (eg, automatic yearly charge to credit card) if offered to all membership types and at a discounted rate?	Response % (n = 272)
Yes	48.5%
No	51.5%
13. Did you attend the 2008 annual meeting?	Response % (n = 270)
Yes	48.5%
No	51.5%
14. If you did not attend HOPA/ISOPP 2008, please explain why.	Response % (n = 139)
Attended another conference instead	16.5%
No funding available	19.4%
Not able to leave work	37.4%
Other (please specify):	26.6%
<i>Answers: Dates not good this year; Too close to ASCO; Personal/family obligations (7); Family illness--thank you for refunding all my fees!; Venue too expensive (I pick from ASHP, ACCP, HOPA); Did not like location/location inconvenient/expensive (3); Sent staff member; Might attend if more BCOP hours; Was not a member yet; All of the above.</i>	
15. Do you think the current registration fee for the annual meeting reflects the value the meeting provides?	Response % (n = 253)
Yes	77.5%
Yes, but I still could not financially afford to attend	12.3%
No	10.3%
16. What time of year would you prefer that HOPA holds its annual meeting?	Response % (n = 269)
Spring (March, April, May)	40.5%
Early summer (June)	19.0%
Summer (July, August)	10.8%
Fall (September, October)	16.4%
Early winter (November, December)	1.1%
Late winter (January, February)	12.3%
17. My membership dues are currently paid by:	Response % (n = 272)
Myself	78.7%
My employer	21.3%
18. Without affecting your support or membership, do you think dues for HOPA could be increased to:	Response % (n = 271)
Full member, \$125/year; associate member \$63/year, resident/fellow/student \$38/year	47.6%
Full member, \$150/year; associate member \$75/year, resident/fellow/student \$45/year	31.4%
Full member, \$175/year; associate member \$88/year, resident/fellow/student \$53/year	1.8%
Full member, \$200/year; associate member \$100/year, resident/fellow/student \$60/year	4.4%
Full member, \$300/year; associate member \$150/year, resident/fellow/student \$90/year	0.0%
None - I could not financially afford an increase in dues	14.8%

19. Which of the following methods for educational program delivery would you be interested in utilizing? (check all that apply)	Response % (n = 269)
Live event (meeting, seminar, rounds)	80.7%
Printed material	67.7%
Teleconference	26.4%
Webcast	56.1%
Podcast	17.5%
CD/DVD	43.5%
Online (other than webcast - please specify)	6.7%
<i>Answers: Articles/pdfs available online (6); Online, but not committed to a specific date/time (similar to the review course); Online CE; Audio with slides CE; Access to CD/DVD of live conferences; Similar to other online CE programs; Self-paced CE online reading/tests (not necessarily webcast) (3); Access to annual meeting lectures (for a fee); Articles and newsletters with therapeutic pearls; Short pieces.</i>	
20. What are the barriers in your practice site to having pharmacy technicians join HOPA? (check all that apply)	Response % (n = 253)
Pharmacy technicians are not aware of the organization	48.6%
Cost of membership	62.1%
Cost of annual meeting	45.1%
Program offering	14.2%
Difficult to take time off work	40.3%
Does not view joining HOPA as a benefit to technicians	45.5%
There are no reasonable barriers	11.1%
Other (please specify):	7.5%
<i>Answers: Site does not allow technicians to make chemotherapy; Employer would not support meeting attendance for technicians (2); Not enough benefits for technicians other than annual meeting; I don't know if techs are aware of HOPA; Techs not interested in HOPA (3); I don't interact with technicians/none at our site (5); Nurses mix chemo; We are short-staffed; Techs not specifically assigned to oncology (2); Location (I practice in the UK); There is no generally agreed upon certification for oncology technicians. This would be a fabulous program for HOPA to embrace, similar to the model ONS used in providing certification for nurses.</i>	
21. Does the quarterly HOPA newsletter provide you with information that is relevant to your organization/clinical practice?	Response % (n = 270)
Yes	65.2%
No	4.8%
Cannot evaluate (eg, have not seen the newsletter)	30.0%
22. Are there additional sections you would like to see added to the newsletter?	Response % (n = 221)
Yes	63.8%
No	36.2%
23. If you answered yes, choose which of the following you would find useful. (check all that apply)	Response % (n = 158)
Clinical pearls	93.0%
Book reviews	25.3%
Other (please specify):	15.8%
<i>Answers: Reimbursement resources; Case studies; "Hot topics" on the listserv (4); Routine surveys on agreed upon topics conducted annually; Job postings; interviews of pharmacists and what they do that others may be able to implement; Spotlight on best or unique practices; Patient and medication safety issues; Information relevant to private practice/community oncology; CPD; Research/clinical phase trial updates (2); Current laws in debate; Other oncology meeting opportunities, ie NCCN; Highlight a member...would be good PR and get to know others are doing; Pediatric heme/onc topics/updates; Insurance coding for pharmacists--the basics; ACCP-accredited CE for BCOP; Something like humor that makes it enjoyable to read in addition to clinical info and news; Practice insights; Review section for regulatory/practice issues; More practice highlights; Finance</i>	

HOPA MEMBERSHIP SURVEY, AUGUST 2008 (CONTINUED)

24. What other improvements could be made to the quarterly newsletter?	Response % (n = 19)
<i>Answers: More comprehensive; Summary of interesting topics from the listserv, supported with evidence; Send out newsletter via email instead of having to log on to the website; Updates from the major meetings, such as clinical decision-making updates; Send by regular mail; I haven't received it; More frequent publication—by the time the newsletter is published the clinical info in it has usually been available elsewhere; More on new drugs; Fellow/Resident points-of-views; Availability of research grants; Current data on side effects of drugs in Medwatch; More about pediatrics; Practical info; Discounts on books; Summary of new drug approvals related to oncology; Better information from the committees; More on opportunities to get involved with the organization; Like the new drug reviews done by residents; Summaries of some of the more interesting HOPA list-serve responses; More timely, shorter newsletter, but more frequent (we have a lot to learn from ONS); More frequently; E-mail notification of availability on-line; More information on committee activity.</i>	
25. Regarding the website, do the current tabs allow for easy access of information?	Response % (n = 267)
Yes	94.4%
No	5.6%
26. What improvements could be made to the website? (check all that apply)	Response % (n = 194)
Add links to other websites	42.3%
Rearrange information	6.7%
Increase members-only information	32.0%
Other (please specify):	19.1%
<i>Answers: Archive listserv/make searchable (15); Take away the listserv and replace with blog or message board; The listserv gets a little out of control sometimes; Send out listserv messages in daily digest format; Don't open a new window with each selection on the website; Make it full screen (4); Need to set up listserv that it replies only to the person sending the question; Make more concise & organized (2); Make easier to navigate; More resources specific to chemotherapy and supportive care drug administration; More resources to train new staff members to oncology pharmacy; More resources for community oncology pharmacists; ADD LINKS TO: Guidelines, BCOP info/renewal, more CE (3), CE for BCOP renewal, oncology-specific websites; CE should explicitly state if applicable to BCOP renewal; Members-only access for ACCP-accredited CE for BCOP certification; Confirmation of electronically submitted changes; if a "same" question is asked on the listserv, maybe attach a link to the former archived responses; Are there going to be slides available online from the 2008 meeting?; There's a website?</i>	
27. Were you satisfied with the information and biosketch provided for each candidate to help guide your decision in this year's Executive Board election?	Response % (n = 237)
Yes	97.9%
No	2.1%
If no, what suggestions for improvement?	
<i>Answers: Please make them SHORTER; Why do we even have elections when in the end (half the time) the board members are chosen or changed by the board itself? New blood is needed on the Board!</i>	
28. Are you satisfied with the process for submitting nominations for the HOPA Awards?	Response % (n = 254)
Yes	63.8%
Not familiar with process	35.4%
No	0.8%
If no, what suggestions for improvement?	
<i>Answers: Many excellent candidates are probably not recognized because of the site that they work or as a result of working in relative anonymity—I would like to see some form of self-nomination or at the very least the ability to nominate candidates without having intimate knowledge of their practice; The process is fine, but when awards are given out at the meeting it would be nice to say more than the persons name—where they practice, a few words from their nomination letter, something like that; I felt that awards were granted on other than merits.</i>	

29. Would you be interested in purchasing professional liability insurance if offered through HOPA?	Response % (n = 268)
Yes	40.7%
No	59.3%
30. What do you see as the benefit(s) of being a HOPA member? (check all that apply)	Response % (n = 270)
BCOP recertification programs	71.1%
Continuing education at the Annual Meeting	81.5%
Listserv participation	73.3%
Networking with colleagues	81.5%
Clinical practice guidelines provided on the website	60.7%
Other (please specify):	4.1%
<i>Answers: Input I have into HOPA programming; HOPA membership helps me prevent burnout - I come back from meetings challenged and excited about new ideas to put into practice; Job listings (2); Support of the profession and specialization; Method to improve oncology pharmacy through organizational means and via networking; I rely on HOPA to increase my knowledge and to collaborate with more experienced practitioners; Being a part of your specialty organization; I get a lot for my HOPA membership compared to other organizations.</i>	
31. What services would you like to see HOPA offer or provide in the future?	Response % (n = 45)
<i>Answers: The BCOP programs should be the first priority for webcasts & allow members of HOPA to access at a reasonable, program-by-program rate. Take control on this!; More BCOP hours (3); Increased opportunities for BCOP credits (4); BCOP recertification CE via web; BCOP study groups/study help (2); Take control of BCOP content/process completely; Patient education materials & dosing algorithms; Manager or clinical coordinator forums; Best practices—centers who have developed true quality metrics; More networking; Resources specific to community practice, hospital practitioners and community/outpatient practitioners; Literature reviews; Info on residencies—listings, accreditation, etc; Reply to emails sent; Regional HOPA affiliations; Research development; Research funding for new faculty and fellows; Legislation and administrative visions for leadership, drug costs, and legal issues with reimbursement; CD of events at major conferences (2008 HOPA/ISOPP conference was the best oncology pharmacy conference I have attended and I would appreciate access to a CD of the live seminars); More CE opportunities other than the annual meeting (2); More local meetings, or twice yearly meetings; Electronic journal club; Unified clinical guidelines; Comprehensive listing of practice/treatment guidelines on website; More guidelines in the format like ONS or ASCO (2); Financial assessment guidelines for treatments; Improve listserv process to allow easy collating of info on one subject; Professional committees such as the ambulatory care setting; Web-based access to annual meeting content for members; ASCO yearly meeting review; Education modules; Career development; Membership category for retired pharmacists; Partner in a very robust way with ONS!; Broader involvement on committee and leadership level with more diverse kinds of oncology pharmacists (other than hospital-based and academic-based); On surveys, add "don't know/haven't observed" option to yes/no; Assistance with setting up pharmacist-run clinics, billing for cognitive services, etc (2); Formation of a pediatric focus area; Spend more time promoting Oncology Pharmacy to other medical professions and to the public; More education from experts (eg, ESAs and Medicare billing) instead of us trying to understand in our individual practices: We need help with day-to-day community issues! Professional Affairs groups: can we continue group with ongoing teleconferences?</i>	
32. How often are you willing to participate in HOPA-sponsored surveys?	Response % (n = 270)
Monthly	20.7%
Every other month	14.8%
Quarterly	35.9%
Semi-annually	18.1%
Annually	10.4%



HOPA UNIVERSITY



A New Website for HOPA-Sponsored Educational Activities

HOPA University is . . .

- A centralized library of HOPA-sponsored educational courses and activities
- Where you go to claim credit for attending HOPA meetings and other educational activities
- A permanent transcript of educational credit you have received through HOPA
- AND MORE!